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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,806	01/25/2002	David Francischelli	M190.135.101	9372

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/29/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,806

Applicant(s)

FRANCISCHELLI ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-31 is/are rejected.
- 7) ☒ Claim(s) 12-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 19, 20 and 22-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Panescu et al ('267).

Panescu et al disclose an electrosurgical system for creating lesions in tissue. In particular, the system includes an instrument with an electrode (16), a power source (12) having multiple power settings, a controller (98) for controlling the operating parameters (i.e. power, time, cooling rate, etc), a source of fluid (50) for cooling the electrode. Panescu et al teach that lesion depth may be controlled empirically or by computer modeling by controlling the power and cooling fluid delivered to an electrode. Tables 1 and 2 (col. 10) show various results of power/cooling combinations and their effect on lesion depth. Columns 9 and 10 discuss the creation of data tables or computer modeling for creating lesion depths. Also, column 11, lines 5-15 addresses the controller which is used to input set desired lesion depths and to identify a desired power lever and treatment time. Column 12, lines 12-25 further discloses the use of the controller to fix various variables (i.e. power, time, cooling) to achieve a desired lesion.

Claims 1-3, 33, 25-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Whayne et al ('411).

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Whayne et al disclose a system analogous to the Panescu et al system. In particular, Whayne et al provide an electrode device for creating predictably sized lesions in tissue. Columns 29 and 30 discuss the use of a controller (32) which stores a relationship between the lesion depth, ablation power level and ablation time. Tables 3 and 4 show various combinations of powers and times which are suitable for providing lesions of predictable depth (column 20). The system includes a catheter with a plurality of electrodes, and a controller with a processor (32) for storing the desired parameters (i.e. look-up table) to provide the desired lesion characteristics.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-11, 15 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267) in view of the teaching of Whayne et al ('411).

The Panescu et al system has been addressed in the previous 35 USC 102(b) rejection. The examiner maintains that Panescu et al teach that an energization time period would be identified for each lesion depth value and power setting as set forth in claim 2. The examples cited by Panescu et al indicate a constant time period (i.e. 120 seconds), but the disclosure clearly indicates that any of the parameters may be chosen based on a table of corresponding values (col. 12, lines 17-25). However, to further strengthen the position, the Whayne et al reference is used as a teaching of specifically

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varying the treatment time to achieve a desired ablation/lesion depth with a given power. Table 3 (column 20) of the Whayne et al reference specifically shows that the time of treatment may be variable and lesion depth is dependent on the combination of various treatment times and energy levels. Hence, Whayne et al expressly teach, in an analogous lesion-depth control system, that variable times may be matched with given power and lesion depth parameters to achieve the desired treatment result.

To have provided the Panescu et al system with a parameter regimen which matched a particular treatment time to set values for power and desired ablation depth for creating controlled lesions in tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Whayne et al, particularly since Panescu et al specifically disclose that any of the parameters may be matched/varied based on given inputs.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267) and Whayne et al ('411) as above and further in view of the teaching of Mulier et al ('553).

The combination of the Panescu et al and Whayne et al teachings has been addressed previously. While Panescu et al disclose an electrode for creating controlled lesions in cardiac tissue, there is no specific teaching of drawing the electrode back and forth across tissue to create the lesion as part of a Maze procedure.

Mulier et al disclose another ablation catheter which includes a distal electrode used to deliver RF energy to cardiac tissue for creating lesions. The lesions are to

reduce conduction pathways in cardiac tissue (i.e. Maze procedure), and Mulier et al teach that it is generally known to move such catheters back and forth across tissue to create such lesions. In particular, the Mulier et al device is provided with a roller electrode which is more smoothly moved across tissue than prior art tip electrodes (i.e. such as taught by Panescu et al).

To have moved the Panescu et al electrode back and forth across tissue to create elongated lesions would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Mulier et al.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267) in view of the teaching of Jackson et al ('874) and Edwards ('877).

Panescu et al fail to specifically disclose a warning signal to indicate the completion of the lesion procedure.

The examiner maintains that it is generally well known in the art to provide electrosurgical systems with warning means (i.e. audible/visual signals) which indicate various conditions of the system such as reaching a desired treatment level, or surpassing a predetermined power level or temperature, etc. In support of this assertion, Jackson et al and Edwards are provided for showing the use of such warning signals. In Jackson et al, an ablation catheter is used to deliver RF energy to cardiac tissue just as in Panescu et al. In particular, Jackson et al provide a warning signal when an undesirable phase shift occurs between the voltage and current signals (col. 6, lines 3-8). Edwards discloses a system for creating controllable lesions in tissue and

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specifically includes a warning signal means for alerting the user of attaining predetermined limits for energy delivery (col. 15, lines 40-50).

To have provided the Panescu et al system with a warning means to alert the user of attaining a desired level of treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Jackson et al.

Allowable Subject Matter

Claims 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sherman discloses another ablation catheter for creating controlled lesions in cardiac tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

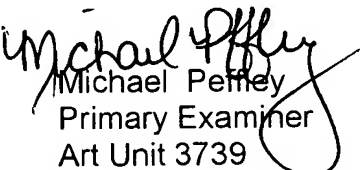
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Perley
Primary Examiner
Art Unit 3739

mp
April 24, 2003